UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ED

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/271,763	03/18/99	BALDWIN	1073.008H

HM12/0524

CANDICE J CLEMENT
HESLIN & ROTHENBERG
5 COLUMBIA CIRCLE
ALBANY NY 12203

EXAMINER	
HSU,G	
ART UNIT	**PAPER NUMBER**
1627	2

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/391,783	Baldwin et al.
Examiner	**Group Art Unit**
Grace Hsu, Ph.D.	1627

Responsive to communication(s) filed on _____ .

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-37* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

X Claims *1-37* are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____ .

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Please Note: *In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is* ***(703) 305-3704****. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Keith MacMillan, Supervisory Examiner at Keith.MacMillan@uspto.gov or 703-308-4614. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.*

1. Claims 1-37 are pending in the current application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 27, drawn to a combinatorial library of formula (I), (T'-L)q-S-C(O)-L'-II', classified in class 549, subclass and in class 436, subclass 518.

II. Claims 15-18, drawn to a pharmaceutical compositions of compounds of formula II, classified in class 549, subclass 396+.

III. Claims 36-37, drawn to a combinatorial library of the formula S-C(O)-L'-II', classified in class 436, subclass 518.

IV. Claims 4-14, drawn to a compound of formula II, classified in class 549, subclass 396 and in class 544, subclass 376.

V. Claims 30, drawn to a compound of formula 14 or 14 a, classified in class 525, subclass 374+.

VI. Claims 31, drawn to a compound of formula 12' or 12a', classified in class 525, subclass 374+.

VII. Claims 32, drawn to a compound of formula 14', classified in class 525, subclass 374+.

VIII. Claims 33, drawn to a compound of formula D, classified in class 525, subclass 374+.

IX. Claims 34, drawn to a compound of formula E, classified in class 564, subclass 61+.

X. Claims 19-20, drawn to a method of administering an effective amount of a compound of formula II, classified in class 549, subclass 396.

XI. Claims 21-26 and 28, drawn to a method of identifying a ligand having a desired characteristic, classified in class 435, subclass 7.1.

XII. Claims 29, drawn to a process for preparing a compound of formula 3, classified in class 562, subclass 453+.

XIII. Claims 35, drawn to a method of synthesizing combinatorial libraries, classified in class 436, subclass 518.

3. The inventions are distinct, each from the other, because of the following reasons:

4. Groups I, II and III represent separate and distinct inventions. Groups I-III are drawn to different products (comprising different compositions, which have biological, therapeutic or some other functional uses; wherein combinatorial libraries comprise compositions or collections based upon different chemical formulas, with two or more compounds). Therefore, Groups I-III have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

5. Groups IV-IX represent separate and distinct inventions. Groups IV-IX are drawn to different compounds (as represented by different chemical structures, which have different chemical and physical properties). Therefore, Groups IV-IX have different issues regarding

patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

6. Groups X-XIII represent separate and distinct inventions. Groups X-XIII are drawn to different processes or methods (which are directed to different purposes, use different materials, recite different method steps for the preparation of different product(s) or lead to different final results). Therefore, Groups X-XIII have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

7. Groups I-III and Groups IV-IX represent separate and distinct inventions. Group IV-IX are drawn to different product compositions (i.e., pharmaceutical compositions or combinatorial libraries,comprised of a different composition or a collection of two or more compounds, which have biological, therapeutic or some other functional uses), while Groups IV-IX are drawn to different compounds (as represented by different chemical structures, which have different chemical and physical properties), Therefore, Groups I-IX have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

8. Groups I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the compound members of the combinatorial library of Group I may be tested or assayed via different methods than by the processes or methods of GroupXI.

9. Groups IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compounds of Group IV may be used in different methods of adminstration, inhibition or treatment, etc. synthesized by alternate synthetic routes in liquid or solid phases using different synthetic organic methods with different starting materials and reagents than by the processes or methods of Group X.

10. Groups V-IX and XIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compounds of Group V-IX may be used in different methods, including different combinatorial libraries synthesis, as intermediates in the synthesis of other compound types, treatment, etc. than by the processes or methods of Group XIII.

11. Group XII is unrelated to Groups I-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

chemical structure of the product prepared via the process of Group XIII is the different from the products and/or chemical structures of Groups I-XI.

12. Group XIII is unrelated to Groups I-IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the product prepared via the process of Group XIII is the different from the products and/or chemical structures of the combinatorial library compound members of Group I.

13. Groups I-IX and Groups X-XI represent separate and distinct inventions. Groups II, III and IV are drawn to products, while Groups X-XI are drawn to different process (which are directed to different purposes, use different materials, recite different method steps for the preparation of different product(s) or lead to different final results). Therefore, Groups I-IX and Groups X-XI have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

14. These inventions are distinct for the reasons above and have acquired a separate status in the art because of their recognized divergent subject matter and/or shown by their different classifications. While some of the aforementioned groups are classified under an identical class/sub-class, the corresponding non-patent literature search remains unaffected. Each of the identified groups may require different searches. For example, methods and products groups require different searches. Therefore, restriction for examination purposes as indicated is proper.

15. This application contains claims directed to the following patentably distinct species of the claimed invention.

16. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species A** of the claimed invention:

Species A	**claim no.**	**A combinatorial library of claim 1, wherein -C(O)-L'-II' is:**
(1)	claim 3	Ia
(2)	claim 3	Ib
(3)	claim 3	Ic
(4)	claim 3	Ib'
(5)	claim 3	Ic'

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

17. If applicants elect the invention of **Group IV**, applicants are required to further elect from the following patentably distinct **Species B** of the claimed invention:

Species B	**claim no.**	**A compound of claim 4, wherein R^{12} is:**
(6)	claim 5	sulfamoylphenyl
(7)	claim 6	p-sulfamoylphenyl

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 4 is generic.

18. If applicants elect the invention of **Group IV**, applicants are required to further elect from the following patentably distinct **Species C** of the claimed invention:

Species C	**claim no.**	**A compound of claim 4:**
(8)	claim 8	as identified by the defined substituents of formula II a of claim 8
(9)	claim 9	as identified by the defined substituents of formula II a of claim 9
(10)	claim 10	as identified by the defined substituents of formula II a of claim 10
(11)	claim 13	as identified by the defined by the formula and substituents of formula of claim 13
(12)	claim 14	as identified by the defined by the formula and substituents of formula of claim 14

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 4 is generic.

19. If applicants elect the invention of **Group IV**, applicants are required to further elect from the following patentably distinct **Species D** of the claimed invention:

Species D	**claim no.**	**A compound of claim 4, of the formula:**
(13)	claim 11	II b
(14)	claim 11	II c
(15)	claim 11	II d

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 4 is generic.

20. If applicants elect the invention of **Group II**, applicants are required to further elect from the following patentably distinct **Species E** of the claimed invention:

Species E	**claim no.**	**A pharmaceutical composition comprising:**
(16)	claim 15	a compound of claim 4
(17)	claim 16	a compound of claim 9
(18)	claim 17	a compound of claim 10
(19)	claim 18	a compound of claim 11

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 15, 16, 17 and 18, respectively, are generic.

21. Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

For search purposes, applicants should provide the chemical structure of each species of claims 1-35, wherein the specific chemical formula substituents of those species are defined either by picture or by expressing the species in terms of the variables of the formula.

22. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

23. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

24. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 6:00 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Keith MacMillan, may be reached at (703) 308-4614. The fax number assigned to

Group 1627 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1627 receptionist whose telephone number is (703) 308-0196.

Grace C. Hsu, Ph.D.
May 22, 2000

BENNETT CELSA
PRIMARY EXAMINER